Dermira, Inc.
Form 8-K
August 08, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): August 8, 2017

Dermira, Inc.

(Exact Name of the Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

000-36668	**27-3267680**

(Commission File Number)	(IRS Employer Identification No.)

275 Middlefield Road, Suite 150

Menlo Park, California (Address of Principal Executive Offices)	94025 (Zip Code)

(650) 421-7200

(Registrant s Telephone Number, Including Area Code)

(Former Name or Former Address, If Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement.

On August 8, 2017 (the ***Execution Date***), Dermira, Inc. (***Dermira***) entered into a license agreement (the ***Agreement***) with F. Hoffmann-La Roche Ltd and Genentech, Inc. (together, ***Roche***) pursuant to which Dermira will obtain exclusive, worldwide rights to develop and commercialize lebrikizumab, a bivalent, monospecific, monoclonal, monoepitopic and humanized IgG4 antibody targeting interleukin 13, for atopic dermatitis and all other indications, except Roche will retain exclusive rights to develop and promote lebrikizumab for interstitial lung disease (the ***Retained Field***) and certain rights to use lebrikizumab for internal research purposes and for *in vitro* diagnostic purposes.

The Agreement includes the following terms, among others:

The Agreement will become effective on the second business day following the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (***HSR***) (such date, the ***Effective Date***).

Dermira will have the following payment obligations under the Agreement:

an initial payment of $80 million to Roche within thirty (30) days after the Effective Date;

a $25 million payment within thirty (30) days after the earlier of September 15, 2018 or the achievement of 50% enrollment in Dermira s first Phase 2 clinical study of lebrikizumab;

a $30 million payment within thirty (30) days after the earlier of December 15, 2018 or the achievement of 100% enrollment in Dermira s first Phase 2 clinical study of lebrikizumab;

a $40 million payment within thirty (30) days after the initiation of Dermira s first Phase 3 clinical study of lebrikizumab;

up to an additional $50 million in payments upon the achievement of milestones related to submission of applications for regulatory approval of lebrikizumab (other than for the Retained Field) in certain territories;

up to an additional $160 million in payments upon the achievement of milestones related to the first commercial sale of lebrikizumab (other than for the Retained Field) in certain territories;

up to an additional $1.025 billion in payments based on the achievement of certain thresholds for annual net sales of lebrikizumab (other than for the Retained Field) ranging from $250 million to $3 billion, with each such potential milestone payment representing between 15% and 20% of the applicable net sales threshold; and

royalty payments representing a range of percentages of tiers of corresponding ranges of annual net sales of lebrikizumab (other than for the Retained Field) that begins in the high single-digits for the first annual net sales tier and increases up to the high teens for annual net sales in excess of $3 billion.

Royalty payment obligations with respect to a given country will commence on the date of the first commercial sale of lebrikizumab (other than for the Retained Field) in such country and end on the later of the date that is (a) ten (10) years after the date of the first commercial sale of lebrikizumab (other than for the Retained Field) in such country, (b) the expiration of the last to expire valid claim of the applicable licensed compound patent rights, Dermira patent rights or joint patent rights in such country covering the use, manufacturing, import, offering for sale, or sale of lebrikizumab (other than for the Retained Field) in such country, (c) the expiration of the last to expire valid claim of the applicable licensed non-compound patent rights in such country covering the use, import, offering for sale, or sale of the product in such country, or (d) the expiration of the last to expire regulatory exclusivity conferred by the applicable regulatory authority in such country for lebrikizumab (other than for the Retained Field).

Roche will receive the net sales of lebrikizumab in the Retained Field less certain amounts associated with Dermira s costs.

Dermira will be solely responsible for its development costs (including all regulatory interactions and conducting and funding of any clinical trials) and commercialization of lebrikizumab (other than in the Retained Field).

Roche or its designees will manufacture, if required, and supply to Dermira lebrikizumab drug substance and drug product pursuant to the terms of a supply agreement to be entered into by the parties. Subject to certain conditions, Roche will have the right to transfer its manufacture and supply responsibilities under the Agreement to Dermira by providing written notice to Dermira. Notwithstanding any such transfer, Roche will retain the right to manufacture the compound and product to exercise its retained rights, including for its own development purposes in the Retained Field, provided that Roche may not (a) enable or license any Roche know-how to a third party to manufacture the compound other than subcontractors performing such manufacturing for use by Roche or Dermira under the Agreement, (b) manufacture a biosimilar product for sale or use in any country until the earlier of four (4) years after the expiration of the royalty term in the country of the first commercial sale of the product (other than for the Retained Field) or the end of the Agreement term, or (c) license any Roche know-how that is disclosed by Roche to Dermira under the Agreement to a third party to manufacture a biosimilar product in any country until the earlier of five (5) years after the expiration of the royalty term in the country of the first commercial sale of the product (other than for the Retained Field) or the end of the Agreement term.

Roche s rights under this Agreement in the Retained Field will be relinquished to Dermira (the ***Roche Reversion***): (a) at Roche s election at any time following 30 days prior written notice to Dermira; or (b) automatically if at any time in a period of eighteen (18) consecutive months Roche is not conducting an active clinical study of lebrikizumab or recurring, bona fide activities aimed at receiving regulatory approval for the compound in the Retained Field, provided that such automatic reversion may not occur within three (3) years of the Effective Date or following regulatory approval for the compound in the Retained Field. Upon the occurrence of the Roche Reversion, all of Roche s rights and all of Dermira s obligations each with respect to the Retained Field will automatically expire, Dermira s payment obligations that had been limited to indications outside the Retained Field will apply to all indications, and where the first commercial sale had applied to the first commercial sale other than for the Retained Field, the first commercial sale will apply to the first commercial sale in any indication.

Subject to certain conditions and limitations: (a) Dermira will have the right to sublicense the rights granted to it under the Agreement; (b) either party may terminate the Agreement in the event of an uncured breach of material obligations by, or certain insolvency events of, the other party or if expiration or termination of the waiting period under HSR has not occurred within six (6) months of the Execution Date; and (c) Dermira may terminate the Agreement at any time, on a country-by-country basis, upon six (6) months prior written notice before the first commercial sale of lebrikizumab (other than for the Retained Field) or upon nine (9) months prior written notice after the first commercial sale of the product (other than for the Retained Field).

Neither party may assign the Agreement or any part thereof prior to the occurrence of both (a) the Roche Reversion and (b) the first commercial sale of lebrikizumab (other than for the Retained Field), without the prior written approval of the other party, which shall not to be unreasonably withheld, conditioned or delayed. Following the occurrence of both the Roche Reversion and the first commercial sale of lebrikizumab (other than for the Retained Field), Dermira may assign the Agreement without Roche s prior consent in the context of a merger, acquisition, sale or other transaction involving all or substantially all of Dermira s assets. A party consummating a change of control transaction will provide written notice to the other party within agreed time periods prior to or following completion of the change of control transaction.

Roche shall indemnify Dermira for losses arising out of (a) Roche s breach of any obligation, representation, warranty, covenant or agreement made by it under the Agreement, (b) development, manufacture or promotion of lebrikizumab in or for the Retained Field, including the sale of lebrikizumab by Dermira for use in the Retained Field, (c) Roche s exercise of certain retained rights, development by Roche in the Retained Field, and promotion by Roche in the Retained Field, or (d) the manufacture of lebrikizumab by or on behalf of Roche.

Dermira shall indemnify Roche for losses arising out of (a) Dermira s breach of any obligation, representation, warranty, covenant or agreement made by it under the Agreement, or (b) Dermira s of development, manufacture, use, handling, storage, sale or other disposition of lebrikizumab (including product liability claims and infringement of third party patents).

The Agreement contains customary representations and warranties made by both parties.

Following the Effective Date and subject to earlier termination, the Agreement will remain in effect until no royalty or other payment obligations under this Agreement are or may become due.

The foregoing summary of the Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the Agreement, which will be filed as an exhibit to Dermira s Quarterly Report on Form 10-Q for the quarter ending September 30, 2017.

Item 7.01 Regulation FD Disclosure.

Dermira anticipates the following corporate milestones in the second half of 2017:

Submission of a New Drug Application (***NDA***) to the U.S. Food and Drug Administration (***FDA***) for glycopyrronium tosylate for the treatment of primary axillary hyperhidrosis.

Launch of Dermira s hyperhidrosis disease awareness campaign.

Dermira anticipates the following corporate milestones in the first quarter of 2018:

Announcement of topline results from CLAREOS-1 and CLAREOS-2, the Phase 3 clinical trials investigating the safety and efficacy of olumacostat glasaretil in patients with acne vulgaris.

Initiation of a Phase 2b dose-ranging study assessing lebrikizumab in adult patients with moderate-to-severe atopic dermatitis, subject to the expiration or termination of waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, as amended, which Dermira anticipates will occur in the third quarter of 2017, and successful program transfer from Roche.

Dermira anticipates the following corporate milestones in the second half of 2018:

Commercial launch of Cimzia® (certolizumab pegol) for the treatment of moderate-to-severe chronic plaque psoriasis, subject to approval by the FDA of the supplemental Biologics License Application submitted by UCB Pharma S.A. to the FDA in July 2017.

Commercial launch of glycopyrronium tosylate for the treatment of primary axillary hyperhidrosis, subject to approval by the FDA of the NDA which Dermira anticipates submitting to the FDA in the second half of 2017.

The foregoing disclosures constitute forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the ***Exchange Act***). Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. You should refer to the section entitled Risk Factors set forth in Dermira s annual and quarterly reports and other filings Dermira makes with the SEC from time to time for a discussion of important factors that may cause actual results to differ materially from those expressed or implied by Dermira s forward-looking statements. The forward-looking statements speak only as of the date of this Current Report on Form 8-K. Dermira undertakes no obligation to publicly update any forward-looking statements or reasons why actual results might differ, whether as a

result of new information, future events or otherwise, except as required by law.

The information in this Item 7.01 is furnished pursuant to Item 7.01 of Form 8-K, and is not deemed to be filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section. The information contained herein and in the accompanying exhibits is not incorporated by reference in any filing of Dermira under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any filings.

Item 8.01 Other Events.

On August 8, 2017, Dermira issued a press release announcing its entry into the Agreement. The press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	**Description of Exhibit**
99.1	Press release dated August 8, 2017.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DERMIRA, INC.

Date: August 8, 2017

By: /s/ Andrew L. Guggenhime
Andrew L. Guggenhime

Chief Operating Officer and Chief Financial Officer

EXHIBIT INDEX

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